DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Electronic Business Machine Co., Ltd.
c/o Mr. Andy Yew
Engineer
North America EBM Technologies, Inc.
1600 Kapiolani Blvd., Suite 1300
HONOLULU HI 96814

JUL 23 2007

Re: K071166
Trade/Device Name: UniWeb™, version 5.0
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 26, 2007
Received: June 29, 2007

Dear Mr. Yew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

JUL 23 2007

INDICATIONS FOR USE STATEMENT

510(K) Number: K071166
Device Name: UniWeb™

UniWeb™ is a device that receives digital images and data from various sources (including but not limited to digital mammography, MR scanners, ultrasound systems, CT Scanners, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across a computer network at distributed locations.

UniWeb™ will be used to display FFDM (Full Field Digital Mammography) post-processed images in DICOM for presentation only formats.

UniWeb™ will NOT utilize digitized film images, only images from FFDM modalities.

UniWeb™ will be utilized for interpretation of mammography images in a primary diagnostic setting.

UniWeb™ will be utilized only on FDA approved monitors used for mammography.
Typical users of this device are trained professionals, including but not limited to physicians, nurses and technicians.

This product will only use lossless compression or no compression when displaying mammography images.

For image diagnosis, this device can only be used by trained professionals.

Prescription Use x AND/OR Over-the-Counter Use: _____

(Please do not write below this line)

(Concurrence of CDRH, Office of Device Evaluation)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071166